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Stakeholder questionnaire on new genomic techniques to contribute to a Commission study requested by the Council

Fields marked with * are mandatory.

Questionnaire on new genomic techniques to contribute to the study requested by the Council

Discussed and finalised in the Ad-hoc Stakeholder meeting on 10 February 2020

Background

The Council has requested [1] the Commission to submit, by 30 April 2021, "a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law" (*i.e.* Directive 2001/18/EC, Regulation (EC) 1829/2003, Regulation (EC) 1830/2003 and Directive 2009/41/EC).

To respond to this Council's request, the Commission is collecting contributions from the stakeholders through the questionnaire below. The study covers all new genomic techniques that have been developed after 2001.

Instructions

For the purpose of the study, the following definition for new genomic techniques (NGTs) is used: techniques that are capable of altering the genetic material of an organism and which have emerged or have been developed since 2001 [2].

Unless specified otherwise, the term "NGT-products" used in the questionnaire covers plants, animals, micro-organisms and derived food and feed products obtained by NGTs for agri-food, medicinal and industrial applications and for research.

Please substantiate your replies with explanations, data and source of information as well as with practical examples, whenever possible. If a reply to a specific question only applies to specific NGTs/organisms, please indicate this in the reply.

Please indicate which information should be treated as confidential in order to protect the commercial

interests of a natural or legal person. Personal data, if any, will be protected pursuant to Regulation (EU) 2018/1725 [3].

[1] Council Decision (EU) 2019/1904, OJ L 293 14.11.2019, p. 103-104, https://eur-lex.europa.eu/eli/dec/2019/1904/oj
[2] Examples of techniques include: 1) Genome editing techniques such as CRISPR, TALEN, Zinc-finger nucleases, mega nucleases techniques, prime editing etc. These techniques can lead to mutagenesis and some of them also to cisgenesis, intragenesis or transgenesis. 2) Mutagenesis techniques such as oligonucleotide directed mutagenesis (ODM). 3) Epigenetic techniques such RdDM. Conversely, techniques already in use prior to 2001, such as Agrobacterium mediated techniques or gene gun, are not considered NGTs.
[3] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295, 21.11.2018, p. 39–98

Guidelines

Please note that the survey accepts a maximum of 5000 characters (with spaces) per reply field. You might be able to type more than 5000 characters, but then the text will not be accepted when you submit the questionnaire. You will also receive a warning message in red colour below the affected field.

You have the option to upload supporting documentation in the end of each section. You can upload multiple files, up to the size of 1 MB. However, note that any uploaded document cannot substitute your replies, which must still be given in a complete manner within the reply fields allocated for each question.

You can share the link from the invitation email with another colleague if you want to split the filling-out process or contribute from different locations; however, remember that all contributions feed into the same single questionnaire.

You can save the draft questionnaire and edit it before the final submission.

You can find additional information and help here: https://ec.europa.eu/eusurvey/home/helpparticipants

Participants have until 15 May 2020 (close of business) to submit the questionnaire via EUsurvey.

QUESTIONNAIRE

Please provide the full name and acronym of the EU-level association that you are representing, as well as your Transparency Registry number (if you are registered)

If the name of the association is not in English, please provide an English translation in a parenthesis

PLATE-FORME TECHNOLOGIQUE EUROPEENNE PLANTES POUR LE FUTUR (‘Plants for the Future’ European Technology Platform), Plant ETP
Transparency Registry number: 167413627983-49

Please mention the sectors of activity/fields of interest of your association

Plant ETP represents the plant sector from fundamental research to crop production and distribution.
As per the Plant ETP statutes, “the mission of the Plant ETP is […] To promote and advocate strategic research and internationally competitive research in Europe as a joint basis for European plant sciences between industry, farmers, and academia.”

If applicable, please indicate which member associations (national or EU-level), or individual companies /other entities have contributed to this questionnaire

Endorsed by the Plant ETP members
Written by members of a Plant ETP working group made up of experts from industry and academia, using input from Plant ETP members, including from the farming community.

If applicable, indicate if all the replies refer to a specific technique or a specific organism

Unless otherwise specified, our replies refer only to plants, including food crops, ornamentals and other model species used in research.

The Plant ETP finds it difficult to meaningfully address NGTs according to the definition provided by this questionnaire: “techniques that are capable of altering the genetic material of an organism and which have emerged or have been developed since 2001”. Therefore, we limit our replies to the category of NGTs that lead to a product (i.e. plant) that could have been obtained by conventional breeding methods, including random mutagenesis (chemical, irradiation), or could appear “naturally” by spontaneous mutations, unless otherwise specified. In other words, such NGTs do not alter the genetic material of an organism in a way that does not occur naturally by mating and/or recombination.

Please not that a reference list is provided as a pdf attachment for each section.

A - Implementation and enforcement of the GMO legislation with regard to new genomic techniques (NGTs)

* **1. Are your members developing, using, or planning to use NGTs/NGT-products?**
  - (●) Yes
  - ( ) No
  - ( ) Not applicable

* Please provide details

Over the past decade, NGTs have revolutionized research globally in both the public and private sectors. Currently in the EU, the Plant ETP industry and academic members are:
• developing NGTs to improve and expand the use of the technology itself, e.g. increase efficiency, broadening the applications of NGTs
• using NGTs and NGT products for gene discovery in R&D projects (industry) and for fundamental and applied research purposes in many fields of plant biology (academia)
• using NGTs to develop NGT products for the market

The Plant ETP members in academia and industry plan to continue with the above mentioned uses and developments of NGTs and NGT products. Our members, particularly those involved in applied research (academia, R&D and breeding companies, industry) would also like to develop NGT products for the EU market. The current ECJ ruling, which has been interpreted as regulating NGT products as GMOs, will seriously hinder this due to the administrative burden, lack of specific regulatory experience with developing complex dossiers, long assessment and approval timelines and costs related to bringing a GMO product to market (Q1Ref1). Under the current legislation, it is expected that a vibrant agricultural innovation ecosystem is at risk. For example, our members from academia would typically develop NGT products in partnership with R&D companies, breeding companies or industry. However, interest from the latter parties to invest in NGT product development for the EU is expected to be limited under the current legislation, and efforts are likely to be targeted at more welcoming regulatory environments.

Plant ETP members of the farming community are not currently using NGT products, as they are not available on the EU market. However, they intend to use varieties that have been developed through breeding processes, including NGTs, if and when they become available and if these varieties:
• provide advantages (increased yield, resilience to biotic and abiotic stress, increased nutrient use efficiency, etc.)
• are affordable
• are accepted by the buyers, i.e. consumers and/or downstream agri-value chain players

* **2. Have your members taken or planned to take measures to protect themselves from unintentional use of NGT-products?**

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please provide details

The Plant ETP members of the farming community have not taken measures against unintentional use of NGT products because there are no such products on the EU market for the time being.

It is the understanding of the ECJ ruling that the use of NGTs and products developed thereof are subject to the obligations of the EU GMO directive. The Plant ETP members from industry and academia, need to comply with relevant EU and national regulations, including those related to contained use of GMOs (work in a laboratory, greenhouse and/or growth chambers), seeking GMO permits for conducting field trials, and applying relevant stewardship measures to prevent spread into the environment of such materials (e.g. destruction of material and collection of flowers prior to pollen dispersal or seed set dissemination) for products developed by NGT´s.

* 2 bis. Have you encountered any challenges?

- (●) Yes
- ( ) No

* Please provide details

Plant ETP members adhere to standard compliance measures to avoid unintentional use of NGT products through robust quality assurance systems. However, there is a risk of unintentional use of NGT products when receiving and using genetic material from countries where NGT products are handled in the same way as products of conventional breeding – as is currently the case for a growing number of countries. To mitigate against such risks, the use of genetic material for research and breeding will need to be restricted to the material currently available inside the EU. It is not a viable option for the Plant ETP members to stop working with genetic material from outside the EU: sharing genetic material worldwide, be it for research purposes or breeding programs, is essential to advance breeding programs directly, as well as to advance understanding of biological processes, that then offers new breeding starting points. Limiting the access of EU players to relevant genetic diversity would thus severely hamper the EU's productivity and competitiveness in research and breeding (Q2Ref1). Because outside the EU the use of NGTs in R&D programs and in public research is growing, differential regulation of NGT products (materials) in the EU and elsewhere is becoming a growing issue for EU parties, including a growing risk of unintentional use. This is especially challenging in view of the difficulties to detect NGT products in third party materials (see our answer to question 4).

Another challenge is that due to the on-going policy discussions in the EU, and the exclusion of NGT products from the scope of GMO regulations in a growing number of countries outside the EU, developers (academia and industry) are handling NGT products as a separate standalone category, i.e. apart from GMO and non-GMO products. The separation in space (infrastructure), equipment and work procedures add further costs and reduces the overall annual productivity of conventional and NGT product development activities.

* **3. Are you aware of initiatives in your sector to develop, use, or of plans to use NGTs/NGT-products?**

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please provide details

As the Plant ETP members represent the entire plant sector across the EU, from fundamental research to crop production and distribution, the answer to this question overlaps in several points with our answer to question 1. Briefly:
• The farming community in the EU is currently not using NGT products, but would like to do so when varieties that have been developed through breeding processes, including NGTs, become available, if these varieties provide advantages compared to current varieties, are affordable and are accepted by the buyers (consumers and downstream agri-value chain players).
• Academia and industry are currently developing and plan to continue developing NGTs, to improve and expand the use of the technologies, and are using NGTs and NGT products for research purposes.
• Industry and academia see the potential of using NGTs to respond more quickly and effectively to demands from downstream parties and society at large. They would therefore like to develop NGT products for the EU market, if they can see a path to market with predictable timelines, costs and supported by proportionate science-based regulation.

Other initiatives include EU and Member State-funded research calls focused on NGTs/ NGT products which have opened across the EU. Here are a few examples of recent research calls:
• PlantED COST Action: CA18111 - Genome editing in plants - a technology with transformative potential (Q3Ref1).
• Biotechnologies for Agriculture (BIOTECH): funded by the Ministry of Agriculture (MiPAF, Italy) and run by the Consiglio per la Ricerca in Agricoltura e l'Economia Agraria (CREA). Funding: € 6 million per year, for three years (started in 2018). Species: horticulture, cereals, fruit, viticulture, olive (Q3Ref2).
• Crops of the future program (2018 -2020): funded by the Federal Ministry of Education and Research (BMBF, Germany) with 26 research projects related to NGT development and optimization (Q3Ref3).
• The Swedish Foundation for Strategic Research, SSF, Agenda 2030 Strategic Research Centre, Call directed towards plant biotechnology (including genome editing). Funding: 60 million SEK (~€ 6 Million). The project will start in 2021 (Q3Ref4).

We are aware of various initiatives to bring NGT products to market, particularly in the US, where certain products developed using NGTs are not in the scope of USDA regulatory oversight for products of biotechnology. Specific examples of NGT products in development or close to market in the US and other countries, can be found here (Q3Ref5). These include:
• Deletion of PPO genes in Agaricus bisporus (white button mushrooms) resulting in non-browning mushrooms. This variety will not be regulated by the USDA, but is still awaiting FDA confirmation of notification (Q3Ref6).
• Direct stacking of sequence-specific nuclease-induced mutations resulting in soybean oil high oleic and low linolenic (Q3Ref7). This variety “Calyno” has been on the market in the US since 2019 (Q3Ref8).
• Groundcherry tomatoes with improved domestication traits such as plant architecture and number of fruits (Q3Ref9).

*** 4. Do you know of any initiatives in your sector to guard against unintentional use of NGT-products?**

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please provide details

Plant ETP is not aware of any current use of NGT products by the farming community in the EU, due to their absence from the market.

Academia, R&D and breeding companies and industry handle NGT products in the EU as GMOs, according to the corresponding regulations in their respective countries and institutes, as described in our answer to question 2.

Due to the fragmented regulation of NGTs globally and the discrepancies between the EU and other countries, it is likely that unintentional use of NGT products and by-products in the EU may occur. Plant ETP refers to a study mandated by DG SANTE in October 2018, following the ECJ ruling, to assess the implications of this ruling for the detection of organisms obtained by NGTs (Q4Ref1). The report states that it will be difficult, if not impossible, to develop detection methods to the same standards as those required by current EU GMO regulations for some NGT products. This raises the question of whether regulations could be implemented in an equal and indiscriminate way for all NGT products, and if discrimination were applied, what the justification would be.

Plant ETP is of the view that where plant products developed using NGTs could have been obtained by other breeding methods, or they contain mutations that cannot be distinguished from mutations that could have occurred spontaneously, they should be excluded from the provisions for detection and identification of GMOs.

* 4 bis. Are you aware of any challenges encountered?

- (●) Yes
- ( ) No

* Please provide details

• Countries outside the EU that do not regulate certain categories of NGTs/NGT products as GMOs, are already growing, selling and consuming NGT products and plan to do this more in the future (see our answer to question 3 and Q4Ref2). These products are currently regulated as GMO in the EU and therefore are subject to the GMO legislations, including import authorizations if these are intended for import into the EU. EU agri-value chain players anticipate increasing operating costs in case they will have to install stewardship measures to avoid these products unintentionally reaching the EU market (closed-loop system). Traceability for products entering EU markets could rely on detection (theoretically), or paper trail documentation and monitoring from the country of origin with the following likely challenges:

o NGT products and by-products may not be monitored and tracked in the country of origin, as they may not be regulated any differently than products obtained by conventional breeding methods

o The possibility of misinformation or lack of knowledge about the techniques used to produce upstream products

• Testing for the presence of NGT products within plant-derived products would depend on the availability of reliable methods. Key challenges are described in the previously mentioned mandated study (Q4Ref1) and include:

o Commonly used GMO detection methods are not applicable to NGT products as they do not contain screenable markers common in GMOs or other transgenes that could be targeted.

o Detection of NGT products could rely on traceability supported by documentation. This requires voluntary transparency from the developers (especially those outside the EU).

o Known NGT mutations may be detectable by PCR, but this has not been shown to be generally the case, especially in bulk grain shipments or food. However, even if detectable, if the mutation is not unique (i.

e. could have been obtained by other means, such as conventional breeding, or arisen spontaneously), it would be impossible to distinguish whether or not the mutation is the result of using an NGT.

o Whole genome sequencing (WGS) has been suggested as a method for detecting NGT products. Whereas this is theoretically possible, many aspects make the use of WGS for this purpose prohibitive (Q4Ref3):

- A complete reference genome comprising all historic and current varieties of each plant species around the globe, would be needed for comparison for each tested product to determine whether the origin is natural or a potential NGT. Technically this is not feasible due to the huge and ever-growing number of varieties that would need to be sequenced. For example, there are more than 2500 varieties of soybeans on the market in the US alone.

- WGS requires the test sample to represent a single genomic sequence in contrast to PCR, which can handle samples with a multitude of different genomic sequences. Furthermore, data analysis of WGS is several magnitudes more complex than PCR and would require labor intensive, high performance computing.

- WGS is much costlier and labor intensive than PCR. It also requires strong technical and bioinformatics expertise.

- WGS is therefore unsuitable to detect low level or adventitious presence of NGT products.

- WGS analyses on test samples will confirm the plasticity of plant genomes and reveal large genetic variation across test samples from e.g. a single shipment. A major challenge will be to assign the observed variation to a specific mutation process, e.g. spontaneous, or induced, and if so by what breeding method these have been developed.

Due to the challenges related to the detection of NGT products and NGT product mingling with non-NGT products, we anticipate that unintentional use may be inevitable as the EU will continue importing plant-derived products from countries that do not regulate NGTs/NGT products in the same way as the EU.

As has already occurred due to GMO regulations, the use of genetic material for research and breeding programs would be restricted to the material currently available in the EU. Such an outcome would isolate the EU from the rest of the world and severely reduce its ability to breed and farm more environmentally sustainable and efficient crops, counter yield penalties due to increased weather volatility and associated pest and disease migration, execute the protein plan, develop more healthy and nutritious food and enable transition to the bioeconomy (Q4Ref4,5).

* **5. Are your members taking specific measures to comply with the GMO legislation as regards organisms obtained by NGTs?**

Please also see question 8 specifically on labelling

- ○ Yes
- ◉ No
- ○ Not applicable

* Please explain why not

Plant ETP is not aware that the farming community is using NGT products in the EU, due to their absence from the market and therefore this question is not applicable to them.

Following the ECJ ruling, the Plant ETP members of both industry and academia follow the provisions of the applicable GMO regulations, including compliance with containment regulations and maintaining a separation of conventional, NGT and GMO product streams, as described in our answer to question 2.

* 5 bis. What challenges have you encountered?

Establishment and maintenance of separate activity streams: the lack of international regulatory clarity has pushed some Plant ETP industry members to handle NGT products as a standalone category, i.e. apart from GMO and conventional products. This separation in space (infrastructure), equipment and operations is adding costs and reduces the overall productivity of the ETP industry members for conventional, GMO and NGT product development activities.

When possible, the ETP members have looked into diagnostic tests to detect and identify their NGT products. However, they have failed so far, facing the issues described in detail in our answer to question 4.

* **6. Has your organisation/your members been adequately supported by national and European authorities to conform to the legislation?**

- ○ Yes
- ◉ No
- ○ Not applicable

* What challenges have you encountered?

The Plant ETP members, throughout the agri-value chain, are of the opinion that they have not been adequately supported by either national or European authorities. This is mostly due to the uncertainty and lack of information regarding the regulation of NGTs available from national and European authorities prior to the ruling (since the discussions started in the EU in 2007) and the deviating, sometimes contradictory, interpretations at the national level, following the ruling. The difficulty of applying the current GMO legislative provisions to NGT products, as described in our answer to question 4, is expected to delay or block parties from applying for market authorization.

Prior to the ECJ ruling, optimism and support for the development of NGTs and NGT products was high across academia, R&D and breeding companies, industry and farmers, as the use of NGTs in breeding would open the way to an unprecedented range of smaller and bigger innovations. Such innovation would address environmental sustainability, impacts of increased weather volatility and associated pest and disease development, the protein plan, development of more healthy and nutritious food, and an enablement of the bioeconomy, and would offer in combination with branding and traceability a lever to improve farm economics structurally. However, the decade-long lack of clarity from the EU prior to the ruling made it difficult throughout the agri-value chain to predict the risks of the foregoing future investment opportunities.

The ECJ ruling and the confusion that has resulted from it, has led to decreased interest and investment in the development of NGT products for the EU market (Q6Ref1).

• In academia, although fundamental research funded by public sources will not be severely affected, the lack of sufficient GMO facilities will likely hamper research in institutes with minimal funding and limited capacity. At least one Member State has already stopped public funding of NGT activities (Austria), with potential knock-on effects on EU research programs. In the case of applied research, which often involves field trials and partnerships with industry, severe consequences of the ruling are already being felt. Interest and investments from industry have dropped and projects currently developing NGT products for the EU market have been delayed and/or put on hold. One example is a variety of starch potato developed in Sweden (Q6Ref2), which underwent (non-GMO) field trials before the ruling and a GMO permit had to be obtained to continue trials in 2019 and beyond. This delayed the project and came at an extra financial cost. Currently 19 out of the 27 EU member states restrict or ban the cultivation of GMO crops. This restriction on GMO field trials, together with the risk of field destruction by activists, severely restricts academia and industry from conducting meaningful R&D on NGT products.
• In industry, the ruling has had a direct impact on R&D project planning and focus (Q6Ref3). This has particularly affected SMEs, such as startup & venture capital dependent R&D, and breeding companies, because they often do not have the necessary regulatory expertise, financial resources and flexibility in time-to-market needed to bring a GMO-rated NGT product to market. History has shown that the EU position towards GMO pushed individual scientists as well as companies like BASF to move their research out of the EU (Q6Ref4).
Throughout the agri-value chain, but particularly in the case of industry and the farming community it is recognized that the inability to market NGTs in the EU under the same regulations as elsewhere in the world, will reduce the competitiveness of the sector vis-à-vis the world at the level of innovation, product performance, product value and overall farming productivity, as well as lower the sector contribution to the 2050 Green Deal targets (Q6Ref5-8).

* **7. Does your sector have experience or knowledge on traceability strategies, which could be used for tracing NGT-products?**

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please describe the traceability strategy, including details on the required financial, human resources and technical expertise

Traceability programs already exist and are being used throughout the agri-value chain, for example for GMO products (Q7Ref1), organic products (Q7Ref2), sustainable palm oil (Q7Ref3), and horticulture products (Q7Ref4).

An essential part of a traceability program for NGT products would be the availability of tests to monitor their presence throughout the agri-value chain. Detection tools may be difficult to put in place for multiple reasons outlined in our answer to question 4. Briefly:

• Where the NGT product is known and is on the market somewhere in the world, reliably detecting its presence requires knowledge of the specific DNA changes in the organism. Even with transparency from the developer, some DNA changes are not unique and can occur by spontaneous mutation or by using conventional breeding methods. It will be impossible to distinguish an NGT product from an almost identical product obtained through conventional breeding methods or having occurred spontaneously (Q7Ref5). It is also questionable how such detection can be reliably performed on bulks and mixtures.

• Where the NGT product is not known, the chance of identifying the DNA change introduced through using NGTs is very low. As explained in our answer to question 4, whole genome sequencing (WGS) is not a solution for the following reasons:

o A complete reference genome comprising all historic and current varieties of each plant species around the globe, would be needed for comparison for each tested product to determine whether the origin is natural or a potential NGT. Technically this is not feasible due to the huge and ever-growing number of varieties and crops that would need to be sequenced, including vegetables, fruit trees, flowers, etc.

o WGS requires the test sample to represent a single genomic sequence in contrast to PCR, which can handle samples with a multitude of different genomic sequences.

o Data analysis of WGS is several magnitudes more complex than PCR and would require labor intensive, high performance computing.

o WGS is much costlier and more labor intensive than PCR. It also requires strong technical and bioinformatics expertise.

o WGS is therefore unsuitable to detect low levels or adventitious presence of NGT products.

o WGS analyses on test samples will reveal large genetic variation across test samples from e.g. a single shipment, due to the plasticity of the plant genome. It will be impossible to determine whether an observed variation has occurred spontaneously or is the result of applying NGTs or any other breeding approach.

We would like to draw a distinction between mandatory labels related to safety and nutritional information and voluntary traceability and labelling schemes, e.g. labels that inform consumers about specific product features such as production method (e.g. organic, fair trade), or location of production (identity preservation schemes). We would like to point out that the current obligation to label GMOs is not voluntary and leads to low consumer acceptance as the label is often confused with health or nutritional labels. Plant ETP is of the opinion that NGT products should remain traceable and labelled when there is a market interest for that (similarly to organic products), but this should not be mandatory.

* **8. Are your members taking specific measures for NGT-products to ensure the compliance with the labelling requirements of the GMO legislation?**

- ○ Yes
- ○ No
- ◉ Not applicable

*

Please describe the measures and their effectiveness including details on the required financial, human resources and technical expertise

NA

* What best practices can you share?

NA

* Please explain why not

NA

* 8 bis. What challenges have you encountered?

NA

* **9. Do you have other experience or knowledge that you can share on the application of the GMO legislation, including experimental releases (such as field trials or clinical trials), concerning NGTs/NGT-products ?**

- (•) Yes
- ( ) No
- ( ) Not applicable

* Please describe for the:

- [x] Agri-food sector
- [ ] Industrial sector
- [ ] Medicinal sector

Agri-food sector

Prior to the ECJ ruling, several field trials with NGT-derived research materials were undertaken in the EU. Some examples are:
• In Sweden, the amylopectin starch potato, prepared using CRISPR-Cas9 technology (Q9Ref1), underwent field trials two years in a row. Following the ECJ ruling, approval for GMO field trials had to be obtained. The trials have been approved and will take place from 2019 to 2023. This is a collaboration between the Swedish Agricultural University (SLU) and the company Lyckeby Starch AB (Q9Ref2).
• In Belgium, maize impaired in its DNA-repair mechanism, prepared using CRISPR-Cas9 technology, was in field trials in 2017 and 2018. Following the ECJ ruling, approval for GMO trials had to be secured to continue trials. This project is run by VIB (Q9Ref3).
• In the UK, Camelina with altered lipid composition using CRISPR-Cas9 technology was planted as a field trial in 2018. The following year, approval for a GMO permit was requested for subsequent trials and was approved for 2019 to 2023. This variety was developed by Rothamsted Research (Q9Ref4).

In the three cases above, field trials were underway at the time of the ECJ ruling in July 2018. This led to widespread confusion about how to handle the field trials that were literally transformed overnight into trials requiring GMO permits. Obtaining permits for GMO trials to continue ongoing research comes at a cost, as well as making the process more burdensome. In support of the permitting process, researchers provided detailed information about the methods used to obtain the lines. Robust detection methods similar to the

methods that accompany the release of GMO field trial materials do not exist.

Considering that there has not been a single new GMO product for cultivation released in the EU in the last decade, the Plant ETP members consider it unlikely that any NGT products will ever make it to the EU market under the current legislative conditions (Q9Ref5, including national opt-outs for GMO cultivation in 19 of the 27 Member States).

Please upload any supporting documentation for this section here. For each document, please indicate which question it is complementing

The maximum file size is 1 MB

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B - Information on research on NGTs/NGT-products

* **10. Are your members carrying out NGT-related research in your sector?**

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please specify including subject, type of research, resources allocated, research location

Following the elucidation of the bacterial defense mechanism CRISPR-Cas and the conversion into a versatile gene editing technology, genome editing has been broadly adopted as a standard experimental procedure in many research labs throughout Europe. The use of this technology in plants was first published in 2013 (Q10Ref1-5). In plant science, introduction of precise mutations using tools such as CRISPR/Cas9, is increasingly considered essential in research projects aimed at studying gene function in complex biological processes. In addition, the ability to apply genome editing across different organisms, facilitates translational research from model species to crops, thereby offering breeders knowledge-driven, predictive breeding reference points. The accelerated pace with which predictive breeding is developing across the globe will be critical in the coming 30 years, to sustain annual yield gains under climate change conditions while addressing the UN Sustainable Development Goals (SDGs). Access to a full repertoire of breeding technologies including NGTs is considered essential. Examples of EU research projects which have reached proof of concept in this area are:

• Low-gluten wheat (ES) (Q10Ref6)
• Non-browning potatoes (AR/SE) (Q10Ref7)
• Potatoes with improved resistance against Phytophtora infestans (SE) (Q10Ref8)
• Potatoes with altered starch quality and improved nutritional uptake (SE) (Q10Ref8)
• De novo domestication of wild tomato species (DE) (Q10Ref9)
• Resistance to powdery mildew in grape (IT) (Q10Ref10)
• Researching effective breeding methods of polyploidy crops, in order to effectively breed for disease resistances, notably in ornamental crops (NL) (Q10Ref11)

It is difficult to estimate the public funding invested in NGT-related research in the EU since 2013. However, dedicated national calls towards the UN SDGs and the agricultural, horticultural and forest sectors that involve the use of NGTs, including CRISPR, have been launched in several countries. Some of these are highlighted below:

• (FR) GENIUS (2012-2020) was awarded € 6 million from the French government to develop NGTs and provide proofs of concept in nine crops (wheat, rice, maize, oilseed rape, tomato, potato, apple, poplar, rose)

and three models (Arabidopsis, Brachypodium, Physcomitrella) (Q10Ref11).
• (IT) Biotechnologies for Agriculture “BIOTECH” was awarded € 6 million from MIPAAF, for three-year sustainable agriculture research plan to be implemented by CREA. The research focuses on genome editing and cisgenesis for grapevine, olive, apple, citrus fruit, apricot, peach, cherry, strawberry, kiwifruit, eggplant, tomato, basil, artichoke, wheat, rice, and poplar trees (Q10Ref12).
• (SE) The Swedish Foundation for Strategic Research, SSF, has opened a call for its Agenda 2030 Research Centers on Future Advanced Technology for Sustainability. This includes funding of SEK 40-60 million for research on Plant Biotechnology, including GMO and CRISPR/Cas9 on agricultural crops and forest trees (Q10Ref13).
• (NL) The DuRPh research program (2006-2016) received € 10 million funding to develop potato varieties resistant to Phytophthera (Q10Ref14).
• Examples of EU-funded projects involving practical application of NGTs are the Newcotiana (Q10Ref15) and the CHIC (Q10Ref16) projects.
Members of the EU seed industry have engaged for several years in evaluating various NGTs, in particular genome editing, by further developing enabling technologies in several crop species, alone or in association with academia, and by applying NGTs as a solution for specific breeding objectives. Breeders use NGTs to better harness genetic diversity, to study the function of genes, and to discover candidate genes and alleles governing desirable traits and phenotypes. These results can be applied to elite genotypes allowing accelerated breeding schemes, and faster adoption of desirable alleles.
Targeted mutation using NGTs can aid the analysis of candidate genes and generate new alleles for traits conferring viral, fungal and insect resistance in most field crops, fruit, vegetable and niche crops. For example, projects to discover candidate host-plant susceptibility genes for targeted mutations could prevent aphid feeding and/or viral transmission in important field crops (e.g. oilseed rape, sugar beet) and reduce the need to apply plant protection products against these pests (Q10Ref17-19).
Similar approaches exist for abiotic stress resistance (e.g. drought, heat, low temperature) (Q10Ref20, 21) as most crops more frequently suffer from extreme weather conditions and accelerated breeding methods will be needed to develop novel traits. This acceleration cannot be achieved using existing breeding methods.
Complex, time consuming and costly regulations governing research in the EU will deter academia and breeders from investing in NGTs, causing EU farmers to cultivate varieties that are less performant than those grown outside the EU.

*** 11. Are you aware of other NGT-related research in your sector?**

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please specify

Examples of NGT-related research in the EU were described in our answer to question 10. Therefore, in our answer to question 11, we will provide examples from outside the EU.

• The USDA database “Am I regulated“ lists “letters of inquiry” seeking advice on the regulatory status of potential products developed using NGTs (Q11Ref1). In the past four years, companies and academic institutions have submitted letters of inquiry for a variety of traits in a number of crops, including nematode resistant soybean, soybean with modified seed composition, citrus tolerant to Citrus Canker, virus resistant tomatoes, long-shelf life lettuce, nutritionally-enhanced wheat, corn with improved resistance to leaf blight, non-browning potato and waxy corn. Several of these traits have progressed to commercial products grown by farmers (e.g. non-browning potato).

• Countries like the US, Canada, Brazil, Argentina and Australia have reduced the regulatory hurdles for

NGT crops in which no foreign DNA sequences have been inserted (Q11Ref2-4). As a result, NGTs have been applied in a range of crops (and other organisms) and used for research and commercial applications. For example:

- o Studies of gene functions (e.g. effect of the RAV2 gene for tolerance of salt stress in rice, Q11Ref5)
- o Improvement of product quality (e.g. improved oil quality in soybean, Q11Ref6)
- o Development of disease-resistant varieties (e.g. virus-resistant cucumber, Q11Ref7)
- o Improved adaptation to abiotic stress (e.g. drought tolerance in maize, Q11Ref8)
- o Increased nutritional quality (e.g. increased protein content in sorghum, Q11Ref9)

• China stands out as a country which invests heavily in NGTs, as is reflected in the leading position of Chinese universities and companies in patents for NGTs. Chinese breeders have performed field trials (>15), mostly in rice, targeting traits ranging from yield increases to disease resistance and tolerance to abiotic stress (Q11Ref5 and references within). Chinese scientists also work with NGT varieties of rape seed, peanut and tomato.

• Russia has declared support to NGTs by launching a US$ 1.7 billion federal research program that will develop ten new varieties of gene-edited crops and animals by 2020 and another set of 20 gene-edited varieties by 2027 (Q11Ref10)

• Disease and pests contribute to 17-30% of global crop losses annually (Q11Ref11). NGTs are therefore widely used to introduce disease and pest resistance into crops and thereby reduce the need for chemical inputs. For EU farmers the ability to reduce chemical inputs without yield loss will become a primary requirement to secure farm profitability in the next decade.
One example illustrating the versatility of NGTs concerns a case that addresses disease from the perspectives of both plant and pathogen: engineered virus strains are used to control Candidatus liberibacter that is devastating citrus plantations in the US by causing the citrus greening disease HLB. At the same time, citrus breeders are using genome editing to introduce resistance to C. liberibacter in citrus trees themselves (Q11Ref12).

• Examples of NGT products that are close to market or have already been approved are given in our answer to question 3.

*** 12. Has there been any immediate impact on NGT-related research in your sector following the Court of Justice of the EU ruling on mutagenesis?**

Court of Justice ruling: Case C-528/16 http://curia.europa.eu/juris/documents.jsf?num=C-528/16

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please describe

Following the ECJ ruling, all stakeholders of the agricultural and associated scientific community were taken aback. The conclusion of the ruling seems to discriminate identical products based on the method used for their development. This interpretation of the ECJ caused deep concern in the academic community, in the farmers' associations, as well as in several branches of the agriculture-related industries.

• For academia, a major consequence will be the limitations in conducting applied research using NGTs. E.g. the very small number of field trials of NGT products across the EU (described in our answer to question 6 and 9), illustrates that outdoor experimentation will be limited for most public and private stakeholders. A second consequence for academia is the growing difficulty in stimulating public-private collaborations as

industry is reluctant to participate in projects with no market perspectives and an uncertain regulatory landscape in the EU.

• Similarly, breeding and seed industries have put on hold plans and projects using NGTs for developing products aimed at EU markets (Q12Ref1). Companies with large operations, active on the global market have moved or are moving their NGT-related R&D outside the EU (Q12Ref2). SMEs do not have similar options, especially those active in breeding European niche crops. This is causing smaller companies to re-direct their R&D objectives, discontinuing NGT projects, while shouldering the loss of time and resources invested over the past few years in NGTs. Beyond these immediate impacts, it is foreseeable that the ECJ ruling will have profound negative, long-term consequences on the scientific competitiveness of EU research as well as on the innovation output of the EU industry.

• Farmers' organizations are aware that the ruling slows down and ultimately hampers the necessary work of academia and industry in offering genetic solutions and competitive varieties using NGTs. They are concerned that EU farmers will not have access to improved varieties that are available in other regions of the world, weakening their ability to compete with imported products grown outside the EU, or to access solutions to address e.g. cropping challenges and consumer demands. Examples include alternatives to certain plant protection products and crops that are more resilient to changing climatic conditions and increasing volatility of the weather.

• Collectively, the European plant science community is alarmed by the impact of the ECJ ruling and the ensuing uncertainties, particularly those affecting young scientists who have serious concerns and demotivation. The interest of students to choose a plant science education will be strongly impacted if innovative technologies such as NGTs are made purposeless in providing societal benefits (Q12Ref3).

*** 13. Could NGT-related research bring benefits/opportunities to your sector/field of interest?**

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please provide concrete examples/data

NGTs encompass a series of technologies emerging from the continuum of progress in life sciences. In their different uses NGTs contribute to improving plant breeding processes from discovery of new traits to increasing genetic gain per breeding cycle, leading to major progress in crop performance and functionality. This translates into benefits for the food, feed and other agricultural value chains and for society as a whole.

• Farmers in the EU expect that the varieties of field, niche, fruit or vegetable and ornamental crops they grow will continue to ensure agricultural and horticultural production, provided that the varieties of the future can cope well with the numerous factors that will increasingly limit crop yield and quality. Because of the increasingly frequent extreme weather conditions and changing climate, farmers need varieties that are more resilient to abiotic stress, fungal, viral and bacterial pathogens, as well as nematode and insect pests, which all contribute to large yield losses. Without easy access to NGTs and their products, scientists and industry in the EU will be unable to deliver such varieties to EU farmers in a timely fashion (Q13Ref1). Regulatory measures that limit the adoption of NGTs in EU agriculture will at best delay migration to more sustainable agriculture and have consequences for the competitiveness of EU's agriculture, food/feed sector and the economy in general.

• The breeding sector regards NGTs as essential for the rapid progress needed to mitigate and adapt to the effects of climate change in the EU (Q13Ref2). The use of NGTs to further domesticate local, orphan or

niche crops has allowed a significant reduction in the timeframe needed (e.g. three years down from ten in the case of domesticated orphan tomato, Q13Ref3). NGTs could help turn previously long-term R&D risk investments into shorter term projects with greater success chances and consequently attract smaller and more diverse players. Access to innovation is particularly critical to small breeding companies and entrepreneurs who could set up a new ecosystem of creative start-ups in EU countries (support to this statement is discussed in our answer to question 18).

• NGTs play a pivotal role in unveiling the function, mode of action and physiological interactions of genes which, in turn, allow acceleration of the discovery of candidate genes governing specific beneficial traits. This knowledge can be used to improve and enhance breeding efficiency, for example by screening for allelic diversity in germplasm collections or by allele conversion in elite lines. Disproportionate regulatory hurdles for NGTs would hinder academic and public research in the EU, preventing the development of and access to new knowledge that underpins rapid deployment of better-performing varieties. NGTs and NGT products are extremely well suited to secure yield stability and quality in all crops. For example: NGT mediated mutagenesis in elite breeding material, as an alternative to introgression breeding, would avoid the penalties in yield and quality, as well as time delays in market launch, since the associated negative effects resulting from linkage drag do not take place (Q13Ref4). To support the above, progress in a multitude of enabling technologies and in a broad range of crop species is needed. This would include whole-plant-regeneration from single cells, accurate base change protocols, other improved editing tools, and DNA-free editing methods. Academia needs to be encouraged to build on the use value of NGTs rather than become restricted by prohibitive regulatory hurdles. Fostering public research on NGTs is a prerequisite for supporting seed companies to bring the traits expected by farmers to the EU market.

*** 14. Is NGT-related research facing challenges in your sector/field of interest?**

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please provide concrete examples/data

A breeder will always choose the most suitable method from the toolbox to achieve their breeding targets. Factors like feasibility, time and costs are paramount. In many cases NGTs offer rapid validation of target genes leading to faster and cheaper translation into products and a shorter time to market. Without the current regulatory hurdles and long timelines, there would certainly be more research and consecutive traits developed with the application of NGTs (e.g. nutrition, digestibility, shelf life).

Without change in the regulatory framework in the EU, we anticipate a decline in applied innovation because of excessive development costs, a lack of acceptance and uncertain timelines for commercialization.

The hurdles facing the sector, and which negatively impact the use of NGTs in research, can be divided into three categories:

1. Regulatory costs and timelines for approval
2. Legal uncertainty over future regulations and timelines
3. Public acceptance of NGT products under the GMO regulation

Considering that there has not been a single new GMO product released for cultivation in the EU in the last decade, it seems unlikely that any NGT product will ever make it to the EU market (Q14Ref1).
Globally, leading nations in this field like China and the US have already identified NGTs as a strategic asset for the future of sustainable agriculture and, consequently have advanced significantly in R&D applications and publications. The EU is now lagging behind, and this puts future EU global competitiveness at risk.

Should the current situation in the frame of the ECJ ruling remain, the possibility that SMEs develop and market NGT products in the EU will be close to zero, since the regulatory and associated costs for steering a GMO dossier successfully through EU assessment and approval procedures as well as the chances of not reaching the market are far too high (also discussed in our answer to question 18).

The JRC-ITPS report in 2011 highlighted the risk of an EU brain and technology drain resulting from regulatory hurdles for NGTs (Q14Ref2). While curiosity-driven laboratory research using NGTs remains possible, applications and innovations arising from such research are stifled by the current EU legislation. In the medium to long term this will reduce funding streams for both basic and applied plant science and lead to a reduced interest to study plant science at universities, while innovation will be lost to countries in which innovation into NGTs can be applied more easily.

* **15. Have you identified any NGT-related research needs/gaps?**

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please specify which needs/gaps, explain the reasoning and how these needs/gaps could be addressed

In our reply we would like to distinguish between scientific needs and gaps related to the improvement and application of the technology, and policy gaps for effective, evidence-driven decision making.

Research and development of NGTs is ongoing; tools are being optimized, and new applications are continuously being discovered. The needs of NGT-related research are both technical and social.

• Technical needs involve optimization and fine-tuning of NGTs for DNA modification. For example, broadening the range of loci and crops accessible for editing. These technical needs are being addressed very rapidly, given the vast number of research groups that work in this field globally.

•The social and policy needs are related to evidence-based decision making, public acceptance, funding, and addressing the disconnect between innovation and environmental policies at the EU level. Since the ECJ ruling, projects that involve the development of NGT products have been put on hold or cancelled altogether, while funding for new projects developing NGT products has declined. There is an urgent need for a clear position from national and EU funding agencies regarding their positions on NGT-related research.

• Furthermore, due to the ECJ ruling, NGT products are considered as GMOs. Societal acceptance of GMO products remains low in the EU. Consumers are unlikely to be able to differentiate between a GMO and an NGT product. Knowing that they are regulated and labelled in the same way, may result in low acceptance of NGT products by consumers. Information on how to differentiate NGT products from GMOs could be helpful in supporting potential commercial applications in the future.

• We see significant gaps in the use of scientific evidence to support decision making. Since the discussions on appropriate regulation of NGTs in the EU started in the mid-2000s, multiple EU bodies (SAM, EU JRC, EFSA, NBT WG from MS) have repeatedly concluded that there is no inherent difference, in terms of risk, associable to a product when it is obtained through NGTs compared to a similar product obtained through conventional breeding methods. We urgently need to address the lack of uptake of scientific evidence in decision making and how technical regulations should continuously be adjusted to take scientific progress and understanding into account.

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C - Information on potential opportunities and benefits of NGTs/NGT-products

*** 16. Could NGTs/NGT-products bring benefits/opportunities to your sector/field of interest?**

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

The Plant ETP members see clear opportunities and benefits related to the use of NGT/NGT-products.

• Two broad and interrelated groups of benefits have been identified
  o significant improvements in analytical quality, analytical capacity and process efficiency for academia and breeders
  o reduction of breeding timelines for new varieties (two impacts: more agile response to changes in farmer demand and higher yield gain per year) and broadening of the range of traits and crops which can be improved

• NGTs have quickly become routine in academia for the generation of mutations in target genes. As the NGTs allow for targeted and precise modification, the quality of the scientific observations has improved significantly as the impact of the modification is observed in a genetic background without other genomic changes. Compared to earlier methods, application of targeted NGTs allows a more accurate and detailed analysis of gene function in a shorter timeframe. It is likely that NGTs will be established in almost all crop species, provided there is a critical mass of academics ready to work on optimizing NGTs for specific crops.

• NGTs are displacing earlier technologies such as those involving ‘cisgenics’ and ‘intragenics’ and random mutagenesis (induced by chemicals or radiation).

• Breeders are incorporating NGTs as part of their toolbox to achieve targeted breeding goals/traits. In many cases NGTs offer better and quicker validation of target genes, leading to lower risk R&D investments and a potential shorter time to market for new varieties.

• If breeders were to address the needs of smaller/niche or regional crops/traits, the establishment of an enabling regulatory environment in the EU would be required as to secure a proper economic return.

• Farmers see the potency of NGTs/NGT-products to accelerate and tailor the breeding process as a vital part of the solution to the intractable production challenges the sector faces: to sustainably produce enough food, fiber, energy and other products for the market, to produce environmental goods and services, to become more resource efficient, and to cultivate crops more resilient to volatile weather conditions, climate change and associated development of new pests and diseases.

• Faster and directed plant breeding is important because it allows farmers to address changing market demands that include plant-based proteins, reducing inputs of plant protection products and other specific

demands for industrial uses. EU farmers urgently require access to an advanced toolset that includes well adapted varieties combined with other technological developments such as precision farming, digital and smart farming, and biocontrol.

* Are these benefits/opportunities specific to NGTs/NGT-products?

- (●) Yes
- ( ) No

* Please explain

The precise introduction of genetic variation using NGTs opens the way to

1) Address research questions that are intractable using other methods
Precision targeting eliminates research bottlenecks for generating test materials and gene knockouts

2) Improve complex commercial traits
o Biofortification, especially vitamin levels, iron bioavailability (through modification of ascorbate levels), amino acid composition of storage proteins, resistant starch composition, removal of toxins in food crops, reduction of the acidity of fruit.
o Reduced disease susceptibility (for example powdery mildew and downy mildew susceptibility) and insect resistance.
o Water use efficiency, flowering time (for terminal drought resistance), and plant architecture for forage /feed crop usage.

3) Accelerate the development of traits
o In tomato, the time to generate specific mutations is reduced to 9 months compared to >5 years needed for conventional introgression (Q16Ref1).
o NGTs may allow new traits to be introduced directly into established varieties, thus reducing the years needed for introgression and eliminating problems of linkage drag.
o For some vegetatively propagated crops (e.g. potatoes, fruit trees, vine grapes, ornamentals), cross breeding is very restricted and time consuming, NGTs offer trait improvements that are not possible with cross breeding, especially through the use of DNA-free editing techniques (Q16Ref2).
o Polyploid crops, where multiple gene copies need to be mutated for a trait to be expressed, benefit from the targeting efficiency of NGTs. An early example of this is the generation of wheat lines resistant to powdery mildew (Q16Ref3).

A pragmatic and proportionate regulatory approach is needed to boost the competitiveness of EU plant breeding and avoid negative impacts on emerging markets such as those in Africa (where countries are positive about the benefits of NGTs to ensure Sustainable Food and Nutritional Security). NGTs provide a unique opportunity for EU farmers to support the ambitious SDG targets, especially those related to climate change and biodiversity, and a secured supply of sustainably produced food, feed and other products.

* **17. Could NGTs/NGT-products bring benefits/opportunities to society in general such as for the environment, human, animal and plant health, consumers, animal welfare, as well as social and economic benefits?**

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

Plant ETP and its members firmly believe that NGTs/NGT products can provide significant benefits for society in general, particularly for the environment, and is a critical enabler of EU welfare in a transition to a fossil-free economy. We believe that the safe use of all innovative techniques at our disposal is necessary to meaningfully contribute to achieving the goals of the EU Green Deal and the UN SDGs. Some examples of the benefits NGTs/NGT products could provide are listed below:

• A rejuvenated and innovative agricultural ecosystem
Technology trends like digitalization, big data, artificial intelligence, automation, and NGTs are transforming the life science sectors including agriculture. NGTs have a place in this list as they are “the” enabling technology that allows to translate an innovation concept into an actual product opportunity. The integration of the foregoing disciplines together with clear goal setting through the Green Deal are the starting basis for the development of a rejuvenated and innovative agricultural innovation ecosystem. This would involve academia, start-ups, breeding and R&D companies, industry and farmers. It would trigger welfare development through venture capital, high profile jobs across the sector, students choosing to study plant science, and deliver innovation addressing societal expectations in, and likely also outside, the EU. Having an unfavorable regulatory framework limiting the use of NGTs in agricultural applications would remove one of the key enablers of this to happen.

• Benefits for the consumer
o Acrylamide is a potential carcinogen that is produced in high-temperature processed potato. Genome editing in commercial potato cultivar Ranger Russet was used to develop lines with lower levels of acrylamide formation when processed (Q17Ref1).
o In Europe, an estimated 1% of the population suffers from coeliac disease (Q17Ref2), an autoimmune disorder triggering immunoreactivity upon ingestion of gluten protein. Wheat with reduced immunoreactivity has been developed using CRISPR/Cas9 (Q17Ref3).
o Vitamin A is an important nutrient that must be taken through the diet. CRISPR/Cas9 has been used to develop rice with enriched beta-carotenoid levels, a precursor of vitamin A (Q17Ref4).
o Ascorbate (vitamin C) is an essential dietary constituent important for immune system function. It also functions as an important antioxidant and improves the bioavailability of iron in the diet. Enhanced ascorbate content of tomato has been achieved by genome editing (Q17Ref5).
o De novo domestication of wild tomato using NGT yielded a 5-fold increase in lycopene (a strong antioxidant) content compared to modern cultivars (Q17Ref6,7)
o Improved dietary fiber in chicory and development of chicory suitable for medicinal applications by producing anti-tumorigenic and anti-inflammatory terpenes (Q17Ref8).

• Resistance to pests and diseases
o In viticulture, growers and producers tend to maintain established, traditional grape varieties. Disease susceptibility is a major problem, resulting in the excessive use of copper-based fungicides, even in organic viticulture. However, breeding for disease resistance takes well over a decade and the new variety is always distinct from the original variety from both quality and regulatory perspectives. Site-directed mutagenesis by NGTs could result in varieties resistant to mildew while maintaining all the desirable features of the original variety. This would reduce the dependency on copper-based fungicides and improve the sustainability of agricultural practices in the wine industry (Q17Ref9).
o Bacterial blight, an important disease in rice, causes substantial yield losses. CRISPR/Cas9 has been used to engineer broad and durable resistance (Q17Ref10).
o Citrus canker, a bacterial disease, causes severe damage to the global citrus industry. CRISPR/Cas9 has been used to develop resistant citrus varieties, something that is not possible to achieve by conventional breeding (Q17Ref11).

• Tolerance to abiotic stress
Drought is the primary cause of agricultural loss globally. Maize varieties with improved grain yield under

field drought stress conditions have been generated using CRISPR/Cas9 (Q17Ref12).

• Product quality traits
o High-amylopectin starch potatoes are suitable for industrial applications and reduce the need for polluting chemical processing which is required for regular starch potato varieties. CRISPR/Cas9 has been used for efficient targeting in tetraploid potato, resulting in improved starch quality (Q17Ref13).
o Waxy maize contains high level of amylopectin with favorable characteristics as thickeners and stabilizers in many food products. Though available for many years, significantly improved waxy maize varieties have been engineered using CRISPR/Cas9 (Q17Ref14).

* Under which conditions do you consider this would be the case?

NGTs and NGT products could contribute substantially to the European Green Deal, in particular the Farm To Fork and Biodiversity strategies, as part of a rejuvenation of the agricultural ecosystem in which digitalization, big data, artificial intelligence, automation and other technology developments serve as enablers.

For example, EU farmers are expected to significantly reduce the use of chemical pesticides, while the EU authorization of many plant protection products have not been renewed. This means that EU farmers cannot rely on the current tools to protect crops from diseases and pests, which puts food security and safety at risk, as well as the competitiveness of EU agriculture. Furthermore, EU farmers will also have to reduce the use of fertilizers. NGTs can be used to develop varieties that are less dependent on plant protection products and high fertilizer input. This would enable EU farmers to ensure crop production, food security and safety at affordable prices for the 446 million EU consumers. Similar challenges apply to the various production systems of ornamentals, in which the use of agrochemicals is high, and the development of disease and pest resistant varieties is urgent.

NGTs and derived crop varieties can also contribute to the UN SDGs, in particular SDG2 (Zero hunger), SDG3 (Good health and well-being), SDG9 (Industry, innovation and infrastructure), SDG11 (Sustainable cities and communities), SDG12 (Responsible consumption and production), SDG13 (Climate action), SDG14 (Life below water) and SDG15 (Life on land).

The role of NGTs in creating a sustainable future was highlighted by the World Resources Institute, which concluded that closing the gaps fully requires many innovations, including in crops. The report states that “A revolution in molecular biology opens up new opportunities for crop breeding. Progress at the necessary scale requires large increases in R&D funding, and flexible regulations that encourage private industry to develop and market new technologies.” (Q17Ref15).

* Are these benefits/opportunities specific to NGTs/NGT-products?

- (●) Yes
- ( ) No

* Please explain

NGTs offer by far the most agile and most effective approach to develop varieties that address upcoming needs from farmers, producers and society without creating undesirable side-effects, e.g. yield penalties, or changes in properties, e.g. nutritional value or taste.

• NGTs make genetic improvement and breeding of new varieties more efficient and faster, with greater gains and accelerated time-to-market (Q17Ref16-22). NGTs offer the potential to breed smaller, more

regionally used crops with small markets, which up to now had been economically unattractive. NGTs offer efficient trait management in crops where conventional breeding is limited, for example potato: Potato has many wild relatives which carry resistance to various diseases. However, these wild species often have different chromosomal structures, making crosses with cultivated potato difficult, if not impossible. NGTs offer the possibility of introducing beneficial traits from wild species into cultivated potato without the drawbacks of conventional breeding (Q17Ref23).

• Conventional mutagenesis has been used successfully for more than 70 years in commercial plant breeding. However, it suffers from the drawback that thousands of background mutations are created, and some of these may have negative effects on crop performance. To remove deleterious mutations, breeders typically need 6-7 generations of backcrossing to reduce the number of background mutations, while retaining the one mutation that gives the breeder the desired trait(s). NGTs offer the possibility to achieve the targeted mutation in a single generation without the high background level of mutations typical for other methods, saving several years of costly and time-consuming development (staff and greenhouse space) (Q17Ref24-26).

• Importantly, the development of novel, and improved techniques in breeding, such as NGTs, does not replace conventional techniques, but complements these. Different techniques have different use values in specific situations, and the existence of a portfolio of techniques gives plant breeders the tools they need to develop innovative, new varieties (Q17Ref27).

* **18. Do you see particular opportunities for SMEs/small scale operators to access markets with their NGTs/NGT-products?**

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

There could be numerous opportunities for SMEs/small scale operators to access markets with NGT products. Below are several examples, although this list is not exhaustive:
• Enhancing protein content of cereals and targeting higher physiological efficiency in crop nitrogen uptake.
• Increasing stagnating cereal yields, notably through adaptation of wheat and barley to climate change.
• Improving the quality of cereal proteins, particularly by increasing the content of lysine, and amino acid needed in pig and poultry feed (Q18Ref1).
• Improving breeding programs for clover, alfalfa, vetch and peas, to meet EU needs to improve the production of protein crops.
• Start-ups promoting improved traits:
  o Taste in Robusta coffee
  o Disease resistance in banana and cacao

The ECJ ruling currently places a heavy regulatory burden on NGT-derived products, making it unattractive for SMEs to pursue this line of innovation in its production. The costs are considered too high, both in terms of time and financial resources needed (Q18Ref2), and the chances to reach the market in reasonable and predictable timelines is low. The attractiveness of NGTs/NGT products is best evidenced by looking at data from the US and Argentina, where 75% of the applications to use NGTs originate from SMEs (Q18Ref3).

Furthermore, since the costs of bringing NGT products to the EU market are considerable if they are considered as GMOs, such costs are viable only for large companies and only for large acreage crops. This means that the niche markets that SMEs often operate in cannot benefit from the use of NGTs, as the costs are too high. If the regulatory hurdles for NGT products were reduced (as they are in the US today) there

would be opportunities for SMEs to gain market access with their NGT crops because the cost of breeding would be in balance with the acreage on which the varieties will be grown, offering the required economic return to justify breeding investments.

Consumer demand for healthy, tasty, nutritious and sustainably produced food creates many opportunities for SMEs to market small scale, differentiating, high value products. However, this requires that NGT products are regulated proportionately to the level of risk associated with the product. The ECJ ruling has placed a heavy and disproportionate regulatory burden on NGT-derived products that puts EU agricultural and horticultural businesses at a competitive disadvantage compared to developers operating outside the EU.

*** 19. Do you see benefits/opportunities from patenting or accessing patented NGTs/NGT-products?**

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

The Plant ETP represents academia, R&D companies, breeders, industry and farmers. Whether or not a member sees benefits and opportunities around patenting and accessing of patented NGTs and NGT products depends on their position in the value chain. Due to the limitations of characters for each response in this survey, it would not be possible to accurately elaborate on the views of each member group. Instead we refer to the survey responses of Plant ETP members EPSO, Euroseeds, COPA and COGECA, as well as the response of EuropaBio, which also represents some Plant ETP members.

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D - Information on potential challenges and concerns on NGTs/NGT-products

*** 20. Could NGTs/NGT-products raise challenges/concerns for your sector/field of interest?**

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

• The ECJ ruling has led to concerns among plant breeders about how to handle breeding materials and plant genetic resources coming from all over the world, where some of those genetic resources might be regulated as GMOs in the EU, but are comparable to or indistinguishable from conventional plants. In the long term, this situation is anticipated to translate into a considerable restriction on the availability and use of source materials for breeding programs. The resulting restrictions on access and use of genetic resources are expected to have significant negative impacts on EU-based breeding companies, especially in terms of their competitiveness internationally, as 95% of the European companies operate at the international level. A reduced competitiveness will diminish profitability below cost of capital and lead to massive consolidation in the sector, likely accompanied with a change of ownership to outside the EU.

• Farmers will face challenges similar to breeders as they would have to restrict the range of varieties they purchase, in order to avoid unintended use of NGTs.

• Academia will face difficulties to substantiate greenhouse results with field trials, due to the limited number of countries allowing GMO field trials. This will hamper the translation of research into innovative plant varieties.

If NGT products remain regulated as GMOs in the EU, extensive screening of imported non-NGT products would be needed to ensure they are "free from" NGTs. However, as discussed in our answer to question 4, an EU-wide approach to identify unknown NGT products and adventitious presence in bulk samples is not feasible.

The differential regulatory status for NGT products globally, and the lack of effective detection methods, will put an unfair burden of screening and monitoring (stewardship measures) on companies. The screening will have a substantial cost element and, as outcomes of screenings are the results of "best efforts" and not of standardized robust detection analyses, the outcomes will cause significant uncertainty about their reliability and completeness. The most pragmatic way forward is that the EU aligns its policies with those of other countries in terms of the regulation of NGTs.

It should also be acknowledged that the current regulation will severely slow down research and innovation in the EU, compared to countries where the use of NGTs is not hampered by disproportionate regulations. This will put all EU stakeholders at a competitive disadvantage. The farming community will most likely bear the brunt of this as they are expected to transition to a more sustainable agriculture to meet the goals of the EU Green Deal, but are not given all the tools to do so.

* Are these challenges/concerns specific to NGTs/NGT-products?

- (●) Yes
- ( ) No

* Please explain

The challenges described are specific to NGTs/NGT products because the use of NGTs, as defined in the beginning of this survey, produces a product that could be obtained by conventional breeding methods or could occur by spontaneous mutation. The difficulty, and in some cases impossibility, of detection springs from the nature of the DNA change they contain, which is not unique and could be obtained by other means. In this case, the risk on unintended use is specific of NGTs/NGT products and will require legislation that is better adapted to this.
Beyond the challenge to reliably identify products of NGTs, a broader challenge is the potential application of discriminatory regulation to product categories that present equal risk to human health and the environment. The prospect of mandatory labelling of NGT products (as per GMO regulations) exacerbates further the disproportionate and discriminatory handling of safe and wholesome products solely on the grounds of what tools were used in their development.

* **21. Could NGTs/NGT-products raise challenges/concerns for society in general such as for the environment, human, animal and plant health, consumers, animal welfare, as well as social and economic challenges?**

- ( ) Yes
- (●) No

* Please explain why not

In general, products developed with the help of NGTs do not carry any novel or specific safety challenges compared to products developed using other breeding methods. This view is supported by numerous reports, including those from bodies of the EU Institutions (Q21Ref1).

The use of NGTs can lead to economic challenges affecting society if NGTs/NGT products are regulated indiscriminately as GMOs. Preventing or delaying development and marketing of NGT products will deny EU farmers timely access to plant varieties addressing rapidly changing weather conditions and the development of associated pests and diseases. This would put sustainable farming and the desired level of productivity and diversification at risk, which will impact consumer choice and price.
If NGTs/NGT products are to be regulated as GMOs, it will prevent the expected reductions in the use of pesticides, because farmers will not be able to timely access the appropriate varieties resistant to pests and diseases. The speed with which pests and diseases migrate across the EU due to changing weather conditions, can technically not be followed by breeding processes unless NGTs, which allow for an agile approach, would be part of the repertoire of breeding tools. Currently, farmers, operators and consumers in parts of the world where NGTs are treated similarly to conventional crops, stand to benefit much more from NGTs than similar groups in the EU (Q21Ref2-4).

It is also important to note that refraining from applying a specific risk regulatory system to the products of NGTs will not mean that these products will go unregulated. Newly developed varieties go through thorough testing (DUS for all food crops, including additionally VCU testing for most field crops) and need approval before they can be released on the EU market. They also remain in the scope of the EU General Food law.

* **22. Do you see particular challenges for SMEs/small scale operators to access markets with their NGTs /NGT-products?**

- (●) Yes
- ( ) No

* Please explain and provide concrete examples and data

• The major concern of SMEs/small scale operators is that if NGT products remain regulated as GMOs, there would be no business incentive to operate on the EU market. The procedures for risk assessment, risk management, authorization and labelling under the current GMO legislation are costly and have lengthy and unpredictable timelines, making it a “non-go” for SME business propositions. In fact, the cost and lengthy and unpredictable timelines are recognized as a major issue by all companies regardless of their size.

• SMEs/small scale operators in the seed sector operate globally in 95% of the cases, and lack the resources to develop parallel R&D pipelines, i.e. one for the EU market with varieties without NGTs, and one for the international market with varieties incorporating NGTs. To stay in business, SMEs are expected to consolidate and/or move their operations and markets to outside the EU. This will impact the diversity of offerings in the EU as well as impact employment. Proof of this trend is illustrated by the recent decision of the potato breeder HZPC to move their research activities to Canada (Q22Ref1). The current ruling has also affected SME research projects, some of which have been discontinued, reduced in scope, changed in market focus or timelines re-evaluated. Consequently, SMEs are losing position while large companies can continue developing and applying NGTs for product development in other parts of the world.

• EU farmers have serious concerns about their timely access to innovation in seed breeding in view of the upcoming production challenges. If the EU were to regulate all products that result from NGTs as it regulates GMOs today, NGTs would cease to be developed in the EU. This would impact the SMEs that typically

dominate in markets driven by consumer demand for high value produce coming from small acreage food crops and the demand for feed crops performing well in the diverse agronomic European conditions. SMEs in the sector would not be able to shoulder the costs of the requirements to bring a GMO to market, or address and handle the lack of public acceptance of GMO products. This could lead to a consolidation of SMEs active in breeding which will restrict the open innovation relationship between breeders and farmers that leads to the development of varieties tailored to the farmers' needs.

• It is vital for public research institutes to continue to be able to access NGTs. It is vital for farmers to be able to have a wide choice of seed suppliers. If the seed market is represented by just a few operators, it could result in higher prices for seeds and lower yields, as crops will not be well adapted to local conditions in different EU regions.

*** 23. Do you see challenges/concerns from patenting or accessing patented NGTs/NGT-products?**

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

The Plant ETP represents academia, R&D companies, breeders, industry and farmers. Whether or not a member sees concerns and challenges around patenting and accessing of patented NGTs and NGT products depends on their position in the value chain. Due to the limitations of characters for each response in this survey, it would not be possible to accurately elaborate on the views of each member group. Instead we refer to the survey responses of Plant ETP members EPSO, Euroseeds, COPA and COGECA, as well as the response of EuropaBio, which also represents some Plant ETP members.

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E - Safety of NGTs/NGT-products

*** 24. What is your view on the safety of NGTs/NGT-products? Please substantiate your reply**

For the purpose of the questionnaire NGTs are defined as techniques that can alter the genetic material of an organism and which have emerged or have been developed since 2001. It is challenging to do a meaningful differentiation between "before" and "after" 2001 in terms of techniques used to alter the DNA of an organism. However, in relation to safety such a criterion does not provide grounds to distinguish on the "level" of safety of the methods or the resulting products.

• One of the challenges arising from the current GMO legislation is its disproportionality in relation to the assessment of the safety risks of the resulting products. DNA changes in an organism are viewed as potential hazards when these are achieved using certain tools, for instance gene editing, while they are considered "safe" if achieved through other tools, such as random mutagenesis. The argument for such distinction in the ECJ ruling was the "novelty" of the methods used, and insufficient evidence for history of safe use.

• An undisputable number of scientific assessments, including many produced by bodies of the EU Institutions, as well as national scientific organizations have shown that potential hazards related to changes in DNA are independent of the methods used to generate them. Such evidence has been largely ignored by EU policy makers. As a consequence, the existing safety legislation is not in line with the advances of scientific understanding and evidence.

• For activities such as plant breeding, where generating genetic diversity via DNA exchanges is the crucial element of the development of new varieties, potential risks have been managed successfully under existing procedures for selection of new varieties, and focus on the safety of the resulting products. More specifically, genetically and phenotypically similar products derived from the use of different techniques – e.g. random mutagenesis, targeted mutagenesis, or different types of crossing - do not result in different levels of risks for the final product. This is reiterated in the latest EFSA draft scientific opinion on site-directed nucleases type 1 and 2 and oligonucleotide-directed mutagenesis (Q24Ref1).

• Plants obtained from targeted mutagenesis could in principle be obtained using random mutagenesis, but with less precision (more DNA modifications than required for the desired traits) and lower efficiency (longer breeding times). It is true that some products developed by targeted mutagenesis may not be generated easily by other breeding methods, but these differences are a testimony to the efficiency of NGTs, not to their lack of safety. Where the resulting phenotypes and uses are comparable, it follows that the risks associated with NGT products are similar to those associated with products derived by conventional methods.

• With the use of NGTs, plant breeding can complement empirical breeding approaches with knowledge-driven, targeted and precise approaches capitalizing on the wealth of biology and genomics know-how being developed across EU and non-EU research institutes and biotechnology companies.

• In the EU, all food products should be safe (EU general food law) by meeting the conditions of the general food law and the environmental liability legislation. The general principle of non-discrimination implies that products that have the same safety profile should be governed by the same legislation.

*** 25. Do you have specific safety considerations on NGTs/NGT-products?**

- ○ Yes
- ◉ No

* Please explain why not

The Plant ETP members cannot identify any unique safety considerations linked to NGTs/NGT-products. Plant ETP's position is supported by a substantial body of evidence from scientific studies of plant genomes, natural variation, knowledge about the plasticity of genomes and the type of changes that occur spontaneously or due to different breeding interventions (Q25Ref1).

• Substantially equal products should be treated equally from a regulatory standpoint.

• Unintended "effects", "off-target" edits/effects are often evoked as a specific issue for NGTs and their by-products. Any DNA modification, or change, outside of the desired target region can be described as an off-target change. However, in the context of plant breeding, NGTs significantly reduce unintended changes compared to the number of changes associated with the use of conventional crossing or selection practices (see also our answer to question 17). This is also concluded in EFSA's draft opinion on the risk assessment guidelines for SDN1/2 (Q25Ref2).

• The increased precision of NGTs compared with many conventional breeding techniques and the reduced amount of background genetic changes lead to products that are as safe as conventional products, which have long records of safe use and meet the requirements of the EU general food law and EU environmental liability legislation.

• The safety of a technique can be assessed only by examining the characteristics of the resulting product, as there is no method of determining the safety of a technique in the absence of considering the resulting product (Q25Ref3). In the case of the application of NGTs in plant breeding, society and the environment are exposed to a seed product and not to the technique by which the product was made. The Plant ETP members consider it appropriate if all breeding outcomes undergo the same checks for safety prior to market launch and that the safety of new breeding techniques (or processes) needs to be revisited in the context of the EU GMO legislation, taking as a benchmark the level of variation and unknown/unintended genetic changes occurring during conventional breeding.

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F - Ethical aspects of NGTs/NGT-products

*** 26. What is your view on ethical aspects related to NGTs/NGT-products? Please substantiate your reply**

Any discussion on ethics of NGTs and NGT-products must be placed in the context of the larger debate on new technologies and the use of knowledge and scientific progress in general. Plant ETP is of the opinion that it is incorrect to single out specific technologies if these do not present any novel ethical challenges as is currently the case for NGTs and their use.
Furthermore, the use of NGTs (as any other technology) raises ethical questions that differ depending on the context of their use and application. It would be more meaningful to address specific outcomes of NGT applications rather than the technology itself.
In relation to EU agriculture, food production and plant breeding, we would like to highlight the following points.

Maintaining the status quo and its implications

• There is an ethical dimension to the safety discussion as operators should refrain from doing harm. This principle has been enshrined in EU legislation through the general food law and the environmental liability directives. In this context it is important to keep in mind that maintaining the status quo is not the optimum way of refraining from doing harm. A regulatory situation that prevents the use of improved technologies may cause more harm than a regulatory situation that promotes technological improvements. Particularly when improved technologies can be applied for environmental, health or societal benefits. It would be unethical to block the use of NGTs and NGT products, that can contribute to more sustainable agriculture and food production and achieving a carbon-neutral economy by 2050.

• We believe that using advancements in knowledge and the ensuing new techniques to address existing societal and environmental challenges is highly ethical. For example, the use of NTGs and resulting products to address evolving consumer demands, food quality and security issues, or as part of the solution towards

reduction of the use of plant protection products should be considered ethical objectives. Or rather: not using these techniques would be unethical.

• Climate change is a serious concern for all of us. If temperature rises are not contained, the consequences for future generations will be unpredictable. This should weigh heavily in an ethical assessment. Plant breeding innovation alone cannot solve the challenges of changing climate, but the situation is so serious that all measures should be employed unless there are substantial evidence-based arguments not to do so. Accelerated varietal development is essential for adaptation to and mitigation of climate change.

Objective and independent scientific recommendations

• There has been substantial concern about the products of gene technologies, voiced by activist groups and reflected in public opinion. For ethical reasons, it is important that these concerns are taken into account. However, there are other ethical concerns related to policy approaches to the products of NGTs in the EU. It is ethically problematic that objective and independent scientific recommendations, as presented by EFSA, HLG-SAM, JRC and many other high-level and expert bodies, are consistently overlooked. Along the same lines, it is not ethically defendable to undertake EU-wide policy actions to position the EU across sectors as a leader in scientific knowledge development and innovation, motivate millions of citizen to engage, and at the same time not use the acquired knowledge to develop policies and regulations, such as those related to NGTs and NGT products, that allow to capitalize on these efforts.

• A regulatory situation that prevents or delays the development and marketing of plant varieties that have been developed using NGTs and carry substantial environmental, health and/or economic benefits, and that do not create specific risks is ethically questionable.

Policy influence on third parties

Developing economies have a lot to gain from the use of NGTs and NGT products. Some developing economies tend to look to the EU for the way they would want to regulate modern breeding technologies. The EU should take this into consideration and promote policies that allow the responsible use of NGTs and NGT products. Policies that have the effect of restricting the adoption of technologies that promote socio-economic development in developing countries, particularly when there is no scientific justification, is also ethically questionable.

*** 27. Do you have specific ethical considerations on NGTs/NGT-products?**

- (●) Yes
- ( ) No

* Please explain

Ethics of not applying improved technologies and advancement of knowledge

• Ethical questions are not limited to the question of whether to use a technology, but must also consider the consequences of not using a technology – and what the benefits are of a given product for a pursued goal (environmental, preventive health, societal, land-use, farm-level economics, etc.).

• In view of this, ethical considerations concern the current regulatory situation leading to a delayed adoption of NGTs in research and breeding, as well as respective product development. Plant ETP agrees with the statement from EASAC “that the potential costs of not using a new technology, or being slow in adoption, must be acknowledged. There is no time to lose in resolving the problems for food and nutrition security in

Europe“ (Q27Ref1).

• This was also addressed by the Danish Ethics Council which concluded in its statement on GMO AND ETHICS IN A NEW ERA “that it also raises the question of whether it is ethically problematic if the legislation obstructs the development and marketing of GMOs, e.g. those with positive effects, if they are not deemed more risky than similar conventional varieties” (Q27Ref2).

Freedom of choice

• Freedom of choice is an important principle with strong ethical implications. There are consumers that demand labelling of GMO products to be allowed the choice to not buy these. It cannot be overlooked that there are also consumers who actively choose to buy GMO products, as well as the products of NGTs, as these are often associated with reduced environmental impact (Q27Ref3), improved farmer economy (Q27Ref4) and higher nutritional quality (Q27Ref5). It is ethically problematic to deny consumers the right to make active choices that are beneficial to the environment and to their own health.

• It is equally ethically problematic that farmers who want access to improved seeds are denied this. Farmers are constantly struggling to deliver large amounts of high-quality products, while protecting their crops against pests, diseases and unfavorable weather conditions, and at the same time minimizing the impact of farming on the environment. It is therefore imperative to give farmers access to crop varieties that have been improved to meet such challenges.

Equal access to technology

It is ethically problematic from the point of view of equal access to technology. Should the products of NGTs be subject to the provisions of the GMO legislation, this would result in SMEs/small scale operators being effectively excluded from using NGTs for the EU market, and this would actively work against a particular segment of the market (Q27Ref6).

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G - Consumers' right for information/freedom of choice

*** 28. What is your view on the labelling of NGT-products? Please substantiate your reply**

Plant ETP and its members believe in the right of consumers to full transparency and labelling that guarantees that consumers have accurate and honest information. However, we are concerned that the labelling of NGT products may be misleading or confusing, particularly in cases where the product is comparable to a product obtained by conventional breeding methods. Our arguments are as follows:

• Labels do not usually include information about how a product was created upstream of the farm. To do so for some products, in this case NGT products, and not for other products would be discriminatory. If the breeding process used to develop a product is deemed an important consumer choice option, consumers would need to be better acquainted with breeding technologies in general, so that they can make informed choices about what they are willing to buy/eat and labelling should be applied in a non-discriminatory fashion.

• There is currently a tendency of over-labelling of products throughout the EU. A consumer market study funded by the EU and published in December 2013 identified over 900 food labelling schemes across Europe (Q28Ref1). At the same time, consumers were found to lack knowledge about food labelling schemes and wanted to get more information. This contradiction demonstrates the need to reduce and standardize labels in the EU and to create better clarity for consumers. Adding another label to the plethora of labels will likely increase consumer confusion, particularly if other products are not labelled similarly, i.e. production methods upstream of the farm.

• Implementing new/extra labelling requirements may lead to additional flows of identity-preserved goods across the value chain. This will drive up consumer prices as it increases costs, affects trade, requires extension of storage, processing and production infrastructure and equipment. At the same time, it also creates idle capacity of infrastructure and equipment, reduces shelf space at retailors, creates additional waste, and would also hinder the use of by-products in side-streams.

• If a label for NGTs is to be implemented in a mandatory way, Plant ETP requests that such a label also highlights the benefits that the use of NGTs has brought to the product, when appropriate (e.g. lower environmental impact due to improved water or nutrient use efficiency, improved nutritional composition, etc.).

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H - Final question

*** 29. Do you have other comments you would like to make?**

- (●) Yes
- ( ) No

Please provide your comments here

Ultimately, the objective must be to allow EU farmers to take advantage of the sustainable opportunities offered by innovation in breeding techniques. Such innovation will enhance the uniqueness of the EU agricultural model.

• The shift from process-based to product-based legislation for modern biotechnology is a concept that has wide support in the scientific community (Q29Ref1-4). Each NGT product should be analyzed and discussed by experts on a case-by-case basis, according to strict scientific criteria. The decision on ascertaining the correct regulatory approach should also be proportionate to the risks. The only feasible way to estimate risk is to evaluate the traits of an organism. There is no valid method of estimating risk of a technology as such. The Swedish Board of Agriculture has expressed this clearly, stating that “The ECJ ruling gives rise to questions regarding when something should be considered to carry an increased risk. For example, is it not reasonable to presume that molecular changes that are exactly the same would carry the same risk, no matter how they were produced? If the safety of an organism cannot be determined based on the molecular changes that it contains and by comparison to other organisms which are known to be safe and which contain the same molecular changes, then how is that supposed to be done?” (Q29Ref5). For further

reading, we recommend a report published by The Dutch Commission on Genetic Modification, which describes the implications of a product-based regulatory system for GMO crops in the EU and reviews the regulatory systems in other countries (Q29Ref6).

• Another example is the proposal of The Advisory Board in Norway suggesting a three-tiered approach for GMOs. The lowest tier would comprise a notification process with confirmation for organisms that could occur naturally or be obtained by conventional breeding. The second tier would comprise organisms containing other species-specific changes and would have an expedited assessment and approval process. Finally, the third tier would comprise modifications that cross the species barriers or involve artificial DNA integration. These would follow the standard GMO assessment and approval process. This proposal is pragmatic and allows a good compromise between the product- and process-oriented approaches (Q29Ref7).

• Most jurisdictions that have already adopted, or are in the process of adopting, legislation applicable to NGTS/NGT products favor a product-oriented approach (Q29Ref8). A comparable approach is embedded in the international Cartagena Protocol for the Convention on Biological Diversity (CP-CBD), through the definition of a Living Modified Organism (LMO) (Q29Ref9). It is important to work towards international harmonization of key regulatory requirements, to reduce barriers for international trade (Q29Ref8,10-11).

• Support from EU authorities would need to tackle outstanding issues such as the definitions of “conventionally used mutagenesis techniques”, “newer mutagenesis techniques”, “long history of safe use”, and the GMO definition itself. Without clarity in definitions, it is nearly impossible to take advantage of scientific progress in biotechnology, as the legal status of the resulting products is unclear. Given the lack of reliably performing methods to indiscriminately identify NGT-derived products, guidance would be welcome on how the EU institutions advise researchers and value chain players to operate. In the EU GMO legislation, the concept of “naturally occurring” is of prime importance in relation to the definition of a GMO. To clarify whether the GMO definition applies to NGT products, it is important to know what actually occurs naturally (i.e. without human intervention). An expert review of genetic alterations that do or do not occur naturally was published recently and provides important insight that should be taken into consideration (Q29Ref12).

• It can also be argued that gene technologies in plant breeding have a long history of safe use. GMOs have been used for commercial products since 1996 and are currently being cultivated in 26 countries on a total of 191.7 million hectares. The accumulated cultivated area since 1996 is 2.5 billion hectares (Q29Ref13). And yet there has not been a single case where any negative effect on humans, domesticated animals, or the environment has arisen as a direct consequence of the technology or breeding process itself (Q29Ref14-19). On the contrary, the varieties that have been developed using GMO technology have had clear environmental (Q29Ref20-22), socio-economic (Q29Ref23-25) and health benefits (Q29Ref26-31).

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